THE CLEVELAND CLINIC

The Cleveland Clinic Lerner College of Medicine
of
Case Western Reserve University

September 9, 2005

The Honorable Sherrod Brown
U.S. House of Representatives
2332 Rayburn House Office Building
Washington DC 20515

Dear Congressman Brown:

I am writing to provide unequivocal and highly enthusiastic support of your bill HR 3696, the "Medical Advertising Reform Act," which is intended to markedly improve the current situation with direct-to-consumer advertising of pharmaceuticals and medical devices in the United States.

One of the most poignant examples of the problem with direct-to-consumer advertising occurred with Vioxx, which was approved by the Food & Drug Administration in May 1999. Using direct-to-consumer advertising, this became the most successful drug launch in the history of the pharmaceutical industry and rapidly skyrocketed to over $2.5 billion of sales per year. However, this marketing success occurred without assurance of the safety of the medicine Vioxx, which carried early concerns for the risk of heart attacks and strokes. It has been estimated that well over 100,000 American citizens sustained a heart attack or stroke due to Vioxx during its 5 ½ year commercial availability (with over 20 million Americans exposed) before the sudden withdrawal of this drug from the market in September 2004, representing the largest prescription withdrawal in history. A very large proportion of these heart attacks, strokes, and deaths could have been prevented by having a 2-year waiting period before any new drug could be promoted using direct-to-consumer advertising. This is one of the most important aspects of your bill, which calls for a 2-year post approval waiting period before a new drug can have direct-to-consumer advertising. This is a remarkably vital step for protection of public health. It is impossible to know the true risk of any new medication until such time that a large population is exposed to the drug. The clinical trials leading to FDA approval are not adequate sized or enroll a fully representative profile of patients to reflect the true risk of a drug once a much larger and "real world" population is exposed. The bill's 2-year provision will provide the necessary additional data for the FDA and manufacturers to collect and validate that a new drug is safe before aggressive direct-to-consumer marketing campaigns can be mounted.

Eric J. Topol, M.D., Provost

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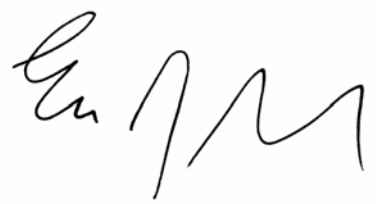
The pre-approval of advertising for pharmaceuticals and medical devices is a critical step that is currently not required by the FDA. Currently, many advertisements with misleading information are released and propagated by television and other media without prior review and approval by FDA. This new feature of the Medical Advertising Reform Act is an essential step to ensure the accuracy of the information disseminated to the public. Furthermore, another outstanding feature of HR 3696 in providing comparative effectiveness of drugs is a laudable and eminently achievable goal. The FDA has a responsibility for making this comparative information available to the public. This concerns the relative effectiveness of drugs in the same class or vis-a-vis other prescription drugs that are used for the same medical condition. Such information is not currently provided but must be in the era of informed consumers for the benefit of the health of our citizens.

Accordingly, I believe that the Medical Advertising Reform Act is vital to advance the interest of the public health. The problem with direct-to-consumer advertising has simulated a "runaway train" with many medications (and more recently with medical devices), best exemplified by the problems with Vioxx, having been heavily promoted to patients who would not derive any benefit and would, on the other hand, be exposed to unnecessary hazard. Beyond this, the economic consequences of wide-scale use of unnecessary or even hazardous prescription medications is of grave concern.

My colleagues and I applaud you for introducing the Medical Advertising Reform Act and we are completely supportive of your efforts in promoting and protecting the health of our citizens.

Sincerely,



Eric J. Topol, M.D.

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